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James Pawlikowski

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EXAMINER

KOPPIKAR, VIVEK D

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/016,506	Applicant(s) PAWLIKOWSKI ET AL.	
	Examiner VIVEK D. KOPPIKAR	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/27/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11,12,14-19,22,24-29 and 31-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11,12,14-19,22,24-29 and 31-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Claims 1, 3-9, 11, 12, 14-19, 22, 24-29 and 31-51 have been examined in this application.

This is a non-final Office action in response to the Request for Continued Examination (RCE) filed on June 27, 2008.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-9, 11, 12, 14-19, 22, 24-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,305,374 to Zdorjkowski in view of US Patent Application Number 2002/0026223 to Riff in view of US Patent Number 5,715,390 to Hoffman in even further view of US Patent Number 5,725,559 to Alt and in even further view of US Patent Number 6,504,825 to Atkins.

(A) As per claim 1, Zdorjkowski teaches a method of upgrading a pressure generating system comprising (Zdorjkowski: Abstract):

providing a pressure generating system including (a) a pressure generator adapted to generate a flow of breathing gas (Zdorjkowski: Col. 3, Ln. 3-27) and (b) a controller that controls operation of the pressure generator and (c) a memory storing a first operating routine,

wherein the controller controls operation of the pressure generator according to the first operating routine, wherein a set of operating features of the pressure generating system is determined based on the operating routine (Zdorjkowski: Col. 3, Ln. 3-23 and Col. 14, Ln. 44-48).

upgrading the pressure generating system by causing the controller to execute a second operating so that the pressure generating system operates according to a second set of operating features (Zdorjkowski: Col. 13, Ln. 19-35).

Zdorjkowski does not teach replacing a first operating routine with a second operating routine nor does Zdorjkowski teach controlling operation of a pressure generator (i.e. medical device) according to a user defined setting nor does Zdorjkowski teach maintaining a data for a plurality of pressure (e.g. pulse) generating system external to the pressure (e.g. pulse) support systems wherein the database includes a serial number unique to each pressure generating system in the plurality of pressure systems, however, these features are taught in Riff (Sections [0022],[0023], [0025], and [0038]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned teachings of Zdorjkowski with the teachings of Riff with the motivation of having a means of enabling a patient to upgrade the software of a medical device with requiring the patient to visit the hospital, as recited in Riff (Section [0006]).

Zdorjkowski in view of Riff do not teach or suggest the other claimed features, however, these are remaining features are all well known in the art as evidenced by Hoffman. Specifically, Hoffman teaches:

wherein an internal access key is associated with each set of operating features of the medical

device (Hoffman: Col. 4, Ln. 52-57);

providing an external device adapted to communicate with the controller;

establishing a communication link between the external device and the controller (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6);

inputting an external access key to the external device; comparing the internal access key

provided by the pressure generating system with the external access key

(Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6); and

enabling upgrading of the pressure generating system by enabling the operating routine to be modified responsive to the internal access key matching the external access key (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the method of Zdorjkowski in view of Riff with the aforementioned features from Hoffman with the motivation of providing a highly secure method of upgrading a device, as recited in Hoffman (Col. 36-38). (Note: Even though Hoffman is directed towards an electric meter the concept taught in Hoffman to upgrade an electric meter is the similar to the concept of the claimed invention. In addition, the concept of securely upgrading a device or controller in Hoffman can be applied to a variety of devices and machines).

Zdorjkowski in view of Hoffman do not teach the following feature which is taught by Alt (Abstract and Col. 7, Ln. 50-Col. 8, Ln. 35)

wherein in the pressure generating system database the (b) one or more operating routines available to each pressure generating system in the plurality of systems, and (c) external access keys associated with the one or more operating routines (Col. 1, Ln. 25-35 and Col. 5, Ln. 25-32).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the teachings of aforementioned references with the teachings from Alt with the motivation of having a means of preventing unauthorized upgrades to medical devices, as recited in Alt (Col. 4, Ln. 23-30). (Note: Alt deals with medical devices generally and therefore it is the position of the Examiner that pressure generating systems are within the scope of Alt.)

The aforementioned references do not teach the following feature which is taught by Atkins (Col. 1, Ln. 62-Col. 2, Ln. 6).

updating the database by assigning a new produce serial number for an upgraded pressure generating system.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above aforementioned references with this teaching from Atkins with the motivation of having a means of uniquely identifying each data processing (e.g. pressure generating) system, as recited in Atkins (Col. 1, Ln. 62-Col. 2, Ln. 6).

(C) As per claim 3, the combined method of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins further comprises, after the enabling step, upgrading the pressure generating system by providing a second operating routine from the external device to

the controller, wherein the controller thereafter executes the second operating routine causing the pressure support system to operate according to a second set of operating features (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

(D) As per claim 4, the combined method of Zdorjkowski in view of Hoffman the first set of operating features includes a first pressure support mode, and wherein the second set of operating features includes a second pressure support mode (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

(E) As per claim 5, in the combined method of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the first pressure support mode is a bi-level pressure support mode, and wherein the second pressure support mode is a bi-level pressure support mode with a timed backup breath delivery capability (Hoffman: Col. 4, Ln. 51-59). The motivation for making this modification to the teachings of Zdorjkowski is the same as set forth above, in the rejection of claim 1. (b) The first pressure support mode is a continuous positive airway pressure (CPAP) support mode and the second support mode is a variable positive airway pressure support mode in which the pressure delivered to the patient varies between inspiration and expiration (Zdorjkowski: Col. 3, Ln. 40-67).

(F) As per claim 6, in the combined method of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the step of establishing the communication link includes providing a hard wired connection between the external device and the controller (Hoffman: Col. 4, Ln. 23-27).

(G) As per claim 7, in the combined method of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the step of inputting the external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device, or reading the external access key from a memory associated with the external device (Hoffman: Col. 4, Ln. 29-31).

(H) As per claim 8, in the combined method of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins further comprises the step of downloading the external access key to the controller responsive to the internal access key being input to the external device, and wherein comparing the internal access key with the external access key takes place in the controller (Hoffman: Col. 4, Ln. 57-63).

(I) As per claim 9, in the combined method of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins each internal access key associated with each set of operating features of the pressure generating system is (1) generated by the controller based on an access key generating algorithm each time the comparing step is to be performed (Hoffman: Col. 4, Ln. 29-33), or (2) stored in advance in a memory in the pressure generating system and recalled from the memory each time the comparing step is to be performed (Hoffman: Col. 4, Ln. 52-65).

(J) As per claim 10, in the combined method of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins, after the enabling step, upgrading the pressure generating system by providing an upgraded operating routine from the external device to the controller, wherein the controller thereafter executes the upgraded operating routine causing the

pressure generating system to operate according to an upgraded set of operating features

(Hoffman: Col. 1, Ln. 5-9).

(K) As per claim 11, in the combined method of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins, each internal access key associated with each set of operating features of the pressure generating system is generated by the controller based on an access key generating algorithm each time the comparing step is to be performed, and further comprising storing the external access key in the pressure generating system as a new internal access key, and causing the controller to generate the new internal access key in a subsequent access key validation process (Hoffman: Col. 4, Ln. 29-42).

(L) As per claims 12-21, the claims repeat features previously addressed in the rejection of claims 1-11, and are rejected on the same basis. (Note: These claims only differ from claims 1-11 in that they are directed towards a system rather than a method).

(M) As per claim 22, Zdorjkowski pressure generating system upgrading system comprising (Zdorjkowski: Abstract): a pressure generating system including:

processing means for controlling at least one operation of the pressure generating system according to a first operating routine executed by the processing means (Zdrojkowski: Col. 3, Ln. 3-23 and Col. 14, Ln. 44-48) , and

memory means, associated with the processing means, for storing the operating routine, wherein a first set of operating features of the pressure generating system is determined based on

the first operating routine, and wherein an internal access key is associated with each set of operating features of the pressure generating system(Zdrojkowski: Col. 5, Ln. 48-57).

Zdorjkowski does not teach replacing a first operating routine with a second operating routine nor does Zdorjkowski teach controlling operation of a pressure generator (i.e. medical device) according to a user defined setting nor does Zdorjkowski teach maintaining a data for a plurality of pressure (e.g. pulse) generating system external to the pressure (e.g. pulse) support systems wherein the database includes a serial number unique to each pressure generating system in the plurality of pressure systems, however, these features are taught in Riff (Sections [0022],[0023], [0025], and [0038]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned teachings of Zdorjkowski with the teachings of Riff with the motivation of having a means of enabling a patient to upgrade the software of a medical device with requiring the patient to visit the hospital, as recited in Riff (Section [0006]).

Zdorjkowski does not teach or suggest the other claimed features, however, these are remaining features are all well known in the art as evidenced by Hoffman.

Hoffman teaches an external device adapted to communicate with the processing means via a communication link between the external device and the processing means, wherein the external device includes means for receiving an external access key, wherein the processing means or the external device includes means for comparing the internal access key of the pressure generating system with the external access key and for enabling upgrading of the pressure generating system by modifying the operating routine to be modified responsive to the internal access key matching the external access key (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the device of Zdorjkowski with the aforementioned features from Hoffman with the motivation of providing a highly secure method of upgrading a device, as recited in Hoffman (Col. 36-38). (Note: Even though Hoffman is directed towards an electric meter the concept taught in Hoffman to upgrade an electric meter is the similar to the concept of the claimed invention. In addition, the concept of securely upgrading a device or controller in Hoffman can be applied to a variety of devices and machines).

Zdorjkowski in view of Hoffman do not teach the following feature which is taught by Alt (Abstract and Col. 7, Ln. 50-Col. 8, Ln. 35)

maintaining a database for a plurality of systems, wherein the database includes (a) a product identifier unique to each pressure generating system m the plurality of systems, (b) one or more operating routines available to each pressure generating system in the plurality of systems, and (c) external access keys associated with each of the one or more operating routine (Col. 1, Ln. 25-35 and Col. 5, Ln. 25-32).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the teachings of aforementioned references with the teachings from Alt with the motivation of having a means of preventing unauthorized upgrades to medical devices, as recited in Alt (Col. 4, Ln. 23-30). (Note: Alt deals with medical devices generally and therefore it is the position of the Examiner that pressure generating systems are within the scope of Alt.)

The aforementioned references do not teach the following feature which is taught by Atkins (Col. 1, Ln. 62-Col. 2, Ln. 6).

updating the database by assigning a new produce serial number for an upgraded pressure generating system.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above aforementioned references with this teaching from Atkins with the motivation of having a means of uniquely identifying each data processing (e.g. pressure generating) system, as recited in Atkins (Col. 1, Ln. 62-Col. 2, Ln. 6).

(O) As per claim 24, in the combined device of Zdorjkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the processing means is adapted to receive a second operating routine from the external device responsive to the external access key matching the internal access key, and wherein the processing means thereafter executes the second operating routine causing the pressure support system to operate according to a second set of operating features (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

(P) As per claim 25, in the combined device of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the first set of operating features corresponds to a bi-level pressure support mode, and wherein the second set of operating features corresponds to a bi-level pressure support mode with a timed backup breath delivery capability (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6). The motivation for making this modification to the teachings of Zdorjkowski is the same as set forth above, in the rejection of claim 1. (b) The first pressure support mode is a continuous positive airway pressure (CPAP) support mode and the second support mode is a variable positive airway pressure support mode in which the pressure delivered to the patient varies between inspiration and expiration (Zdorjkowski: Col. 3, Ln. 40-67).

(Q) As per claim 26, in the combined device of the Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins communication link is a hard wired connection between the external device and the processing means (Hoffman: Col. 4, Ln. 23-27).

(R) As per claim 27, in the combined device of the Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the external device includes a keypad by which the external access key is manually entered into the external device (Hoffman: Col. 4, Ln. 29-31).

(S) As per claim 28, in the combined device of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the external device is adapted to download the external access key to the processing means, and wherein comparing the internal access key with the external access key takes place in the processing means (Hoffman: Col. 4, Ln. 52-65).

(T) As per claim 29, in the combined device of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the processing means is adapted to generate each internal access key associated with each set of operating features of the medical based on an access key generating algorithm executed by the processing means each time an access key validation is required (Hoffman: Col. 4, Ln. 29-33).

(U) As per claim 30, in the combined device of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the external device upgrades the pressure generating system by providing an upgraded operating routine from the external device to the processing means responsive to an upgrade being enabled, wherein the processing means thereafter executes the upgraded operating routine causing the pressure generating system to operate according to an upgraded set of operating features (Hoffman: Col. 1, Ln. 5-9).

(V) As per claim 31, in the combined device of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins the processing means generates each internal access key associated with each set of operating features of the pressure generating system based on an access key generating algorithm each time an access key validation process is to be performed, stores the external access key in the pressure generating system as a new internal access key, and generates the new internal access key in a subsequent access key validation process (Hoffman: Col. 4, Ln. 29-42).

4. Claims 32-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdrojkowski in view of Riff in view Hoffman and in further view of Alt in view of Atkins and in further view of US Patent Number 6,094,702 to Williams et al.

(A) As per claim 32, Zdrojkowski teaches a method of upgrading a pressure generating system(Zdrojkowski: Col. 25.Ln. 2-6).

Zdrojkowski does not teach replacing a first operating routine with a second operating routine nor does Zdrojkowski teach controlling operation of a pressure generator (i.e. medical device) according to a user defined setting nor does Zdrojkowski teach maintaining a data for a plurality of pressure (e.g. pulse) generating system external to the pressure (e.g. pulse) support systems wherein the database includes a serial number unique to each pressure generating system in the plurality of pressure systems, however, these features are taught in Riff (Sections [0022],[0023], [0025], and [0038]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned teachings of Zdrojkowski with the teachings of Riff with the motivation of having a means of enabling a patient to upgrade

the software of a medical device with requiring the patient to visit the hospital, as recited in Riff (Section [0006]).

However, Zdrojkowski does not teach the following features which are well-known in the art as evidenced by Williams:

providing an upgrade request from an upgrade requester to a pressure generating system supplier, wherein the upgrade request includes a first product identifier associated with the medical device to be upgraded and a requested upgrade of the pressure generating system(Williams: Col. 3, Ln. 43-57);

maintaining a database, available to the pressure generating system supplier, that includes the first product identifier for the pressure generating system and an external access key associated with both the pressure generating system and an available upgrade from the one or more for that pressure generating system (Williams: Col. 3, Ln. 57-64);

accessing the database, by the pressure generating system supplier, to determine an external access key associated with both the pressure generating system to be upgraded and the requested upgrade (Williams: Col. 3, Ln. 53-64).

updating the database to indicate that the pressure generating system having the first product identifier has been upgraded with the desired upgrade (Williams: Col. 7, Ln. 14-23).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Zdrojkowski with the features of Williams with the motivation of providing a means of installing resources into a system that are not enabled when a system is sold, as recited in Williams (Col. 2, Ln. 56-58).

The combined method of Zdrojkowski in view of Williams does not teach or suggest the following steps which are well known in the art as evidenced by Hoffman:

providing the external access key to the pressure generating system(Hoffman: Col. 4, Ln. 52-57); comparing the external access key with an internal access key associated with the medical device (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6);

enabling an upgrade of the pressure generating system responsive to the internal access key matching the external access key (Hoffman: Col. 4, Ln. 52-Col. 5, Ln.6).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the method of Zdorjkowski with the aforementioned features from Hoffman with the motivation of providing a highly secure method of upgrading a device, as recited in Hoffman (Col. 4, Ln. 52-Col. 5, Ln. 6). (Note: Even though Hoffman is directed towards an electric meter the concept taught in Hoffman to upgrade an electric meter is the similar to the concept of the claimed invention. In addition, the concept of securely upgrading a device or controller in Hoffman can be applied to a variety of devices and machines).

Zdorjkowski in view of Hoffman do not teach the following feature which is taught by Alt (Abstract and Col. 7, Ln. 50-Col. 8, Ln. 35)

maintaining a database for a plurality of systems, wherein the database includes (a) a product identifier unique to each pressure generating system m the plurality of systems, (b) one or more upgrades available to each pressure generating system in the plurality of systems, and (c) external access keys associated with each operating routine (Col. 1, Ln. 25-35 and Col. 5, Ln. 25-32).

At the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the teachings of aforementioned references with the teachings from Alt with the motivation of having a means of preventing unauthorized upgrades to medical devices, as recited in Alt (Col. 4, Ln. 23-30). (Note: Alt deals with medical devices generally and therefore it is the position of the Examiner that pressure generating systems are within the scope of Alt.)

The aforementioned references do not teach the following feature which is taught by Atkins (Col. 1, Ln. 62-Col. 2, Ln. 6).

updating the database by assigning a new produce serial number for an upgraded pressure generating system.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above aforementioned references with this teaching from Atkins with the motivation of having a means of uniquely identifying each data processing (e.g. pressure generating) system, as recited in Atkins (Col. 1, Ln. 62-Col. 2, Ln. 6).

(B) As per claim 33, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the step of providing the external access key to the pressure generating system includes providing the desired upgrade to the upgrade requester via a distribution media or a electronic communication link (Williams: Col. 3, Ln. 64-67).

(C) As per claim 34, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the step of providing the external

access key and the desired upgrade includes providing the external access key on a first medium and providing the desired upgrade on a second medium (Hoffman: Col. 4, Ln. 52-65).

(D) As per claim 35, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the step of comparing the external access key with an internal access key takes place in the pressure generating system to be upgraded (Hoffman: Col. 4, Ln. 57-63).

(E) As per claim 36, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the step of updating the database includes providing a second product identifier (serial number) associated with the pressure generating system (Hoffman: Col. 4, Ln. 47-51).

(F) As per claim 37, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the pressure generating system includes a controller that controls operation of the pressure generating system according to an operating routine executed by the controller (Zdrojkowski: Col. 3, Ln. 3-23), wherein a set of operating features of the pressure generating system is determined based on the operating routine, wherein the internal access key is associated with each set of operating features of the medical device; and wherein providing the external access key to the medical device comprises: providing an external device adapted to communicate with the controller (Hoffman: Col. 4, Ln. 17-42), establishing a communication link between the external device and the medical device, and inputting an external access key to the external device (Hoffman: Col. 4, Ln. 17-42)

(G) As per claim 38, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams, after the enabling step, upgrading the pressure generating system by providing an upgraded operating routine from the external device to the controller, wherein the controller thereafter executes the upgraded operating routine causing the pressure generating system to operate according to an upgraded set of operating features (Hoffman: Col. 1, Ln. 5-9)

(H) As per claim 39, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams comprises the step of providing the upgraded set of operating features to the external device from the pressure generating system supplier (Hoffman: Col. 1, Ln. 5-9).

(I) As per claim 40, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams each internal access key associated with each set of operating features of the pressure generating system is generated by the controller based on an access key generating algorithm each time the comparing step is to be performed, and further comprising storing the external access key in the pressure generating system as a new internal access key, and causing the controller to generate the new internal access key in a subsequent access key validation process (Hoffman: Col. 4, Ln. 17-42).

(J) As per claim 41, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the pressure generating system is a pressure support system comprising a pressure generating system adapted to generate a flow of breathing gas, wherein the controller executes a first operating routine to control the operation of

the pressure generating system according to a first set of operating features (Zdrojkowski: Col. 3, Ln. 3-23).

(K) As per claim 42, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams, after the enabling step, upgrading the pressure generating system by providing a second operating routine from the external device to the controller, wherein the controller thereafter executes the second operating routine causing the pressure support system to operate according to a second set of operating features (Hoffman: Col. 1, Ln. 5-9).

(L) As per claim 43, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the first set of operating features includes a first pressure support mode, and wherein the second set of operating features includes a second pressure support mode (Zdrojkowski: Col. 3, Ln. 51-58).

(M) As per claim 44, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the first pressure support mode is a bi-level pressure support mode, and wherein the second pressure support mode is a bi-level pressure support mode with a timed backup breath delivery capability (Zdrojkowski: Col. 14, Ln. 43-48). The motivation for making this modification to the teachings of Zdrojkowski is the same as set forth above, in the rejection of claim 1. (b) The first pressure support mode is a continuous positive airway pressure (CPAP) support mode and the second support mode is a variable positive airway pressure support mode in which the pressure delivered to the patient varies between inspiration and expiration (Zdrojkowski: Col. 3, Ln. 40-67).

(N) As per claim 45, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the step of establishing a communication link includes providing a hard wired connection between the external device and the controller (Hoffman: Col. 4, Ln. 17-24).

(O) As per claim 46, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the step of inputting an external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device, or reading the external access key from a memory associated with the external device (Hoffman: Col. 4, Ln. 29-31).

(P) As per claim 47, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams the step of comparing the internal access key with the external access key takes place in the controller (Hoffman: Col. 4, Ln. 52-Col. 5, Ln. 6).

(Q) As per claim 48, in the combined method of Zdrojkowski in view of Riff in view of Hoffman in view of Alt in view of Atkins in view of Williams each internal access key associated with each set of operating features of the pressure generating system is (1) generated by the controller based on an access key generating algorithm each time the comparing step is to be performed (Hoffman: Col. 4, Ln. 29-33), or (2) stored in advance in the pressure generating system and recalled from memory each time the comparing step is to be performed (Hoffman: Col. 4, Ln. 23-25).

(R) As per claims 49-51, the claims repeat features previously addressed in the

rejection of claims 32-48, and are rejected on the same basis.

Response to Arguments

5. Applicant's arguments filed on June 27, 2008 have been fully considered but they are not persuasive. The applicant's arguments will be addressed in sequential order as they were presented in the "Remarks" section filed on June 27, 2008.

(1) The applicants argue that the '374 patent does not teach or suggest causing a controller to execute a second operating routine so that the pressure generating system operates according to a second set of operating features. This argument is now moot in view of the newly added Riff reference.

(2) In response to applicant's argument that '390 is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the '390 patent is analogous to the '374 patent because the '390 patent deals broadly with upgrading electric devices and the device and system of the '374 patent is a device which runs electronically.

(3) Applicants argue that the '559 patent does not teach providing a database which is external to the pressure support system nor does not '559 patent teach a means whereby a serial number is unique to each pressure generating systems. However, this argument is now moot in view of the newly added Riff and Atkins references.

(4) The applicants argue that the claims recite updated the database by assigning a new product identifier for an upgraded pressure generating system and that this step is equivalent to giving an upgraded product a new serial number and that this does not correspond to providing a unique identifier for a segment of data. This argument is not moot in view of the rejection overly the newly added Atkins reference.

Conclusion

6. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Jerry O'Connor, can be reached at (571) 272-6787. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

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direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

9/23/2008

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3626